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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/597,659

08/02/2006

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P400757

4520

46155 7590 12/24/2009
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EXAMINER

MERENE, JAN CHRISTOP L

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

12/24/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/597,659	Applicant(s) ZEITANI, JACOB	
	Examiner JAN CHRISTOPHER MERENE	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/2/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This is the initial Office action based on the 10/597,659 application filed on August 2, 2006, which is a 371 of PCT/IT2005/00076 filed on February 15, 2005, which also claims Foreign Priority to IT RM2004.A00082 filed on February 16, 2004.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Italy on February 16, 2004. It is noted, however, that applicant has not filed a certified copy of the IT RM2004.A000082 application as required by 35 U.S.C. 119(b).

Election/Restrictions

4. Applicant's election without traverse of Group I (Claims 1-13) in the reply filed on October 13, 2009 is acknowledged. Claim 14 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 13, 2009.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **Claims 1-13** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites "which device" in lines 2 and "which member" in lines 3, which is grammatically awkward, unclear and indefinite. It is unclear

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if the applicant is claiming another member or the same member. Claim 5 recites the limitation "clamping means" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 6 recites the limitation "U shaped projecting portion" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 8 recites the limitation "claming means" in line 3. There is insufficient antecedent basis for this limitation in the claim. The examiner will treat these claims with art as best understood in view of the 112 rejection.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

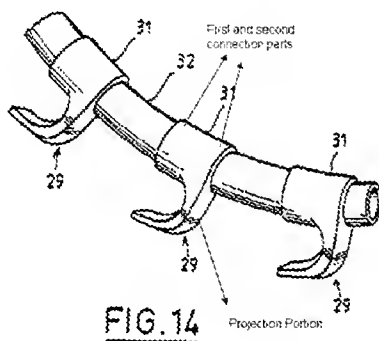
8. **Claims 1, 3, 4, 13** are rejected under 35 U.S.C. 102(b) as being anticipated by Assaker US 5,620,444.

Regarding **Claim 1**, Assaker discloses a sternum reinforcing device to be used after a sternotomy or a sternal fracture, which device comprises

at least an elongated member apt to be used as a unit of a reinforcing group, which member is designed to be located on a surface portion of an anterior longitudinal lateral edge of a sternum and is provided with a first and a second connection parts,

aid first connection part of said elongated modular member being adapted to join with a second connection part of a preceding elongated member of the reinforcing group along the longitudinal lateral edge of the sternum,

said second connection part of said elongated member being adapted to join with a first connection part of a following elongated member of the group along the same longitudinal lateral edge of the sternum said elongated modular member being further provided with a projecting portion designed to be fitted in an intercostal space adjacent to the longitudinal lateral edge of the sternum (as seen in Fig below, where the first and second connection parts can be joined to other second and first connection parts of another elongated member).



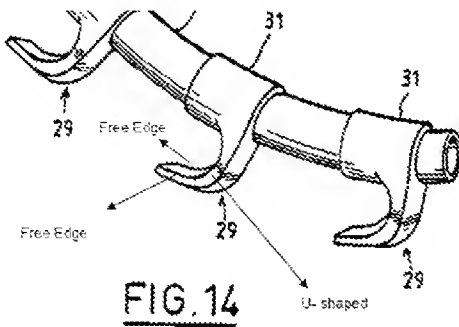
Regarding **Claim 3**, Assaker discloses the elongated member is made from a biocompatible, shaped and bent plate material (see Col 5 lines 30-35, where the device is made from a biocompatible material such as titanium, which is a known plate material and where the device is bent, see projection portion above in claim 1).

Regarding **Claim 4**, Assaker discloses the projecting portion is a body portion at right angles to the connection parts (as seen in Fig below, where the projecting portion projects downward at a right angle from the connection parts).

Regarding **Claim 13**, Assaker discloses the body portion is U-shaped having parallel free edges, orthogonally bent outwards, to enclose between them a clamping

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means of the elongated member to same sternum (as seen in Fig below, where the body is u shaped with parallel free edges).



9. **Claims 1-2, 9-12** are rejected under 35 U.S.C. 102(b) as being anticipated by Longfellow US 2,486,303.

Longfellow discloses a sternum reinforcing device to be used after a sternotomy or a sternal fracture, which device comprises

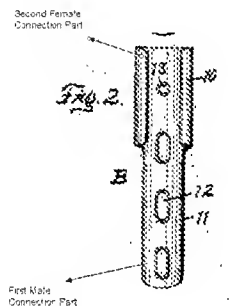
at least an elongated member apt to be used as a unit of a reinforcing group, which member is designed to be located on a surface portion of an anterior longitudinal lateral edge of a sternum and is provided with a first and a second connection parts,

said first connection part of said elongated modular member being adapted to join with a second connection part of a preceding elongated member of the reinforcing group along the longitudinal lateral edge of the sternum,

said second connection part of said elongated member being adapted to join with a first connection part of a following elongated member of the group along the same longitudinal lateral edge of the sternum said elongated modular member being further provided with a projecting portion (#14) designed to be fitted in an intercostal space

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adjacent to the longitudinal lateral edge of the sternum (as seen in Fig below, Col 2 lines 1-15, where the first and second connection parts can be joined to other second and first connection parts of another elongated member), wherein the connection parts are apt to form a prismatic coupling with corresponding connection parts (as seen in Fig below, where the second female part can connect with a male part of another device and where the first male connection can connect with a female part of another device), wherein the first male connection part has a rectangular flat cross section (as seen in Fig below and Fig 3) and can be slide into a female part (see Fig below where the first male connection part can slide into a female part if one chooses to do so), wherein the second female connection part has a hollow channel shaped cross section (as seen in Fig below and see Col 2 lines 10-15).



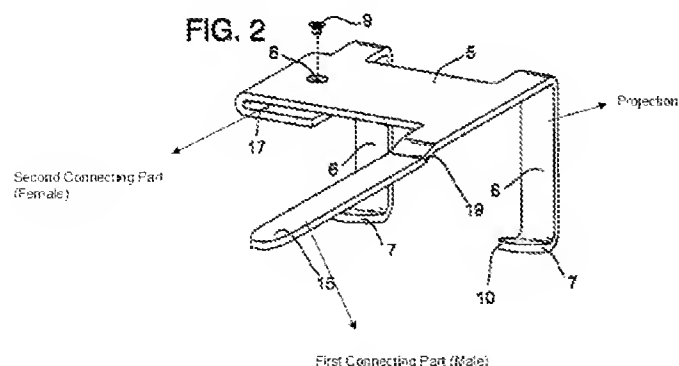
10. **Claims 1-4, 6, 9-13** are rejected under 35 U.S.C. 102(b) as being anticipated by Miller US 6,540,769.

Regarding **Claims 1-3, 9-12**, Miller discloses a sternum reinforcing device to be used after a sternotomy or a sternal fracture, which device comprises

at least an elongated member apt to be used as a unit of a reinforcing group, which member is designed to be located on a surface portion of an anterior longitudinal lateral edge of a sternum and is provided with a first and a second connection parts,

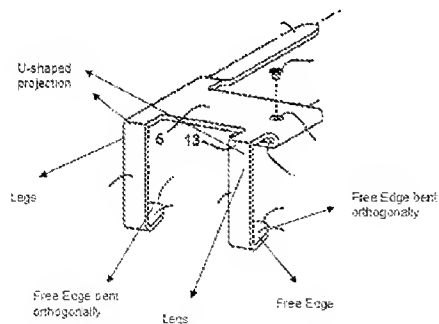
said first connection part of said elongated modular member being adapted to join with a second connection part of a preceding elongated member of the reinforcing group along the longitudinal lateral edge of the sternum,

said second connection part of said elongated member being adapted to join with a first connection part of a following elongated member of the group along the same longitudinal lateral edge of the sternum said elongated modular member being further provided with a projecting portion designed to be fitted in an intercostal space adjacent to the longitudinal lateral edge of the sternum (as seen in Fig below, where the first and second connection parts can be joined to other second and first connection parts of another elongated member), wherein the first connecting part that is flat and has a rectangular cross section and is male, the second connecting part is a female with a hollow channel (#17 as seen in Fig below), wherein the device is made out of biocompatible material (see Col 7 lines 25-28).



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Regarding **Claims 4, 6, 13**, Miller discloses wherein the projecting portion for the intercostal space is a body portion of the elongated member extending between said connection parts and at right angles to them, wherein free edges of the U-shaped projecting portion extend from the projecting portion in the form of legs which can be fitted in the intercostal space of the thorax of a patient, laterally to the sternum, and bent in a mutually opposite direction, on the internal side of the thorax, the body portion is U-shaped having parallel free edges, orthogonally bent outwards, to enclose between them a clamping means of the elongated member to same sternum (as seen in Fig above in claim, where the projection extends at a right angle and see Fig below, where a u-shaped projecting portions form legs which are bent and at opposite directions to one another to form a u shape and where the free edges are orthogonally bent outward).



Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Assaker US 5,620,444 in view of Wagner et al US 5,989,250.

Assaker discloses the use of a wire (#25) that is clamped to the device but does not disclose the wire is made out of stainless steel.

However, Wagner discloses the use of a stainless steel wire (#12), where stainless steel is known for its biocompatibility and rigidity (see Col 8 lines 26-30).

It would have been obvious to one having ordinary skill in the art at the invention was made to modify wire of Assaker to be made out of stainless steel in view of Wagner because stainless steel is known for its biocompatibility and rigidity.

Conclusion

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone

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number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jan Christopher Merene/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733